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IS 5022 (1989): Sterilizers, instruments (table model) [MHD 14: Hospital Planning]

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IS 5022 : 1989
(Reaffirmed 2004)
Edition 4.2
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Indian Standard

STERILIZER, INSTRUMENTS, TABLE MODEL

(Third Revision)

भारतीय मानक

निर्जर्मक, उपकरण, टेबल मॉडल

(तीसरा पुनरीक्षण)

(Incorporating Amendment Nos. 1 & 2)

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BUREAU OF INDIAN STANDARDS
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Price Group 2

FOREWORD

This Indian Standard (Third Revision) was adopted by the Bureau of Indian Standards on 15th May 1989, after the draft finalized by the Hospital Equipment Sectional Committee had been approved by the Medical Equipment and Hospital Planning Division Council.

This standard was first published in 1969 and subsequently revised in 1973 and 1979. The important changes which have been carried out in this revision are in dimension of handle link, load requirements for tray, current carrying capacity and alternative thermostatic requirements.

This edition 4.2 incorporates Amendment No. 1 (May 1993) and Amendment No. 2 (January 1996). Side bar indicates modification of the text as the result of incorporation of the amendments.

For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test or analysis, shall be rounded off in accordance with IS 2 : 1960 'Rules for rounding of numerical values (*revised*).' The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

Indian Standard

STERILIZER, INSTRUMENTS, TABLE MODEL

(Third Revision)

1 SCOPE

1.1 This standard covers structural and functional requirements of boiling type table model instruments sterilizer for disinfecting different types of instruments used in clinics and hospitals.

1.2 Only the sterilizers which are used in places other than the anaesthetic-gas atmosphere come under the purview of this standard.

1.3 This method does not give sterility since spores are not necessarily killed in the process. The method is, however, satisfactory for most general disinfection.

2 REFERENCES

2.1 The Indian Standards listed below are necessary adjuncts to this standard:

IS No.	*Title*
IS 302 : 1979	General and safety requirements for household and similar electrical appliances (*fifth revision*)
IS 1342 : 1986	Oil pressure stoves (*fourth revision*)
IS 2787 : 1986	Multi-burners oil pressure stoves (*second revision*)
IS 4159 : 1983	Mineral filled sheathed heating elements (*second revision*)
IS 4827 : 1983	Electroplated coatings of nickel and chromium on copper and copper alloys (*first revision*)
IS 4905 : 1968	Methods for random sampling
IS 6911 : 1972	Stainless steel plate sheet and strip (*first revision*)

3 MATERIAL

3.1 All the components other than the drain cock, the element and the thermostat shall be made from stainless steel sheet conforming to Designation 04Cr18Ni10 of Table 1 and of 2B or 2D finish as given in Table 8 of IS 6911 : 1972.

4 DESIGN

4.1 The sterilizer shall consist of a seamless shell, having a hand-operated lid at the upper end. It shall be designed to operate on electricity, gas or kerosene (heat sources) either independently or in combination, as desired by the purchaser.

5 DIMENSIONS

5.1 The nominal inside dimensions of the shell shall be as given in Table 1, subject to a tolerance of ± 2 percent.

Table 1 Internal Dimensions of Sterilizer Shell

All dimensions in millimetres

Size	**Length**	**Width**	**Working Depth**
Small	300	150	125
Medium	430	200	150
Large	510	200	150

5.2 The thickness of the stainless steel sheet used for shell, tray and lid shall be 0.90 mm subject to the tolerances on thickness as specified in the relevant Indian Standard. However, thickness of shell tray and lid shall not be less than 0.70 mm at any place, after drawing and for handle lever, it shall be 3.0 mm. The minimum thickness for handle link-connecting the handle lever and lid shall be 1.5 mm.

6 CONSTRUCTION

6.1 The shell shall be pressed to form a seamless container. The rim shall be so formed so as to prevent excessive steam escape. Provision shall be made at the bottom of the shell to place it, properly on the table.

6.2 Lid and Tray

6.2.1 The lid shall be made seamless, dished and shall be designed to prevent excessive steam escape and restrict the condensate within the shell, but in any case it shall not buckle, warp, or-twist with load. The corners shall be rounded to suit those of the shell. The lid shall open fully (between 55° and 85°) by single operation from its closed position. A provision shall be made to connect the link end of the handle mechanism for simultaneous opening and closing of the tray and lid. At the opening of the lid between 55° and 85° the tray shall be able to come to the top level of the shell.

6.2.2 A mechanism connected to the lid shall be such that when the lid is open, a bracket or rest for instruments tray shall bring the seamless tray well out of the water even when the water is at the highest level. The tray bottom shall be perforated to allow easy drain-out or entrance of water when the tray is being lifted or lowered in the sterilizer. Handles shall be provided for handling the tray and the tray shall be convenient for fitting in or removal from the sterilizer.

When the tray is loaded as given below, with load uniformly distributed, the lid shall close slowly and without bang.

Size	*Load* (N)
Small	20
Medium	30
Large	40

6.2.3 The tray shall be of such a design so as to take a test load as per **6.2.2** without any buckling or twist. The depth of tray shall be *Min* 25 mm

7 FUNCTIONAL REQUIREMENTS

7.1 A drain-out connection shall be provided to facilitate draining of the sterilizer when desired.

7.2 The tap handle knob and lid operating handle shall be fitted with suitable grips of thermally insulating material. The metal parts under the grips shall be completely covered so as not to come in contact with the operator.

8 METHODS OF OPERATION OF STERILIZERS

8.1 Sterilizers shall be capable of operation on the heat sources detailed in **8.2** to **8.4** as selected by the purchaser and shall satisfy the requirements specified therein.

8.2 Electric Operation

8.2.1 Electrically operated sterilizers shall have a single-phase, 3-pin connection and the loading shall comply with the following:

Size (mm)	*Load* (kW)
Small (300 × 150 × 125)	1.00
Medium (430 × 200 × 150)	1.50
Large (510 × 200 × 150)	2.00

An indicator lamp shall be provided on the sterilizer to indicate by glowing when the instrument is 'ON'. The entire electrical circuit shall be insulated from the sterilizer and the leakage current shall be not more than 210 μA, or 300 μA, when tested in accordance with IS 302 : 1979. It shall also be capable of withstanding a high voltage test of 1 000 V for one minute between any point of supply and earth.

8.2.2 The wires used shall be heat resistant and the wiring shall be neatly laid out. The minimum current carrying capacity of wire shall be 15 A.

8.2.3 *Heating Element*

Heating element shall conform to IS 4159 : 1983. It shall be of easily replaceable type and fitted with either built-in ejector device or built-in thermal cut out system.

8.2.4 *Thermostat*

Thermostat shall be capable of ensuring boiling water at sea level with a differential of 5°C. Alternatively, a built-in thermal cut-out with immersion heater may be provided in lieu of thermostat. In that case element may not be necessarily of ejector type.

8.3 Gas Operation

This shall be accomplished by providing suitable gas burners underneath. At the option of the purchaser, a temperature controlling device may be provided so as to control the gas flame and maintain water temperature.

8.4 Kerosene Operation

In this case, oil pressure stove or oil pressure heater shall be provided underneath. The oil pressure stoves and oil pressure heaters shall also satisfy the requirements specified in IS 1342 : 1986 and IS 2787 : 1986.

9 FINISH

9.1 All stainless steel parts shall be finished smooth and polished bright or strain finish reasonably free from wrinkles and buldges.

9.2 The brass cock shall be plated chromium over nickel in accordance with service Grade No. 2 of IS 4827 : 1983.

10 MARKING

10.1 The sterilizers shall be legibly and indelibly marked with the following:

a) Identification mark of the manufacturer;
b) Wattage, voltage, phase and cycle of electrically operated sterilizers;
c) Not to be used in anaesthetizing sites; and
d) Instrument does not give sterility.

10.2 The sterilizer may also be marked with code and serial number.

11 INSTRUCTION MANUAL

11.1 Each sterilizer shall be accompanied by an instruction manual which shall contain information regarding instruction, directions and operation of the sterilizer and routine maintenance and service. It shall contain instruction to use soft water to minimise scaling.

12 PACKING

12.1 As agreed to between the purchaser and the supplier.

13 SAMPLING

13.1 Sampling procedure and criteria for conformity for instruments sterilizers may be as agreed to between the purchaser and the supplier. A recommended sampling plan is given in Annex A.

ANNEX A

(*Clause* 13)

SAMPLING PROCEDURE AND CRITERIA FOR CONFORMITY FOR INSTRUMENTS STERILIZERS

A-1 LOT

A-1.1 In any consignment, all instruments sterilizers of the same design and size and manufactured under similar conditions of production shall be grouped together to constitute a lot.

A-2 SELECTION OF SAMPLE

A-2.1 The number of instrument sterilizers to be selected from the lot shall depend upon the size of the lot and shall be in accordance with col 1 and 2 of Table 2.

A-2.2 These sterilizers shall be selected from a lot at random. In order to ensure the randomness of selection, procedures given in IS 4905 : 1968 may be followed.

A-3 NUMBER OF TESTS AND CRITERIA FOR CONFORMITY

A-3.1 The sterilizers selected at random according to col 1 and 2 of Table 2 shall be subjected to the tests for dimensional, construction, functional requirements and operation of sterilizers. Any sterilizer failing to satisfy any of the tests, shall be considered as defective. The lot shall be considered as conforming to the requirements if the number of defectives found in sample is less than or equal to the acceptance number (*see* col 4 of Table 2) and shall be rejected if it is greater than or equal to the first rejection number (*see* col 5 of Table 2). If the number of defectives lie between the acceptance and first rejection number, the second sample of the same size (*see* col 3 of Table 2) shall be chosen at random and tested. If the number of defectives found in the combined samples is greater than or equal to the second rejection number (*see* col 6 of Table 2), the lot shall be rejected, otherwise the lot shall be accepted.

Table 2 Sample Size and Criterion for Conformity

(*Clause* A-2.1)

Lot Size (1)	First Sample (2)	Second Sample (3)	Acceptance Number (4)	First Rejection Number (5)	Second Rejection Number (6)
Up to 50	5	5	0	2	2
51 ,, 100	8	8	0	2	2
101 ,, 300	13	13	0	2	2
301 ,, 500	20	20	0	2	3
501 and above	32	32	0	3	4

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